REMARKS

Claims 1, 7-10, 14-20, 26-32, 38-40, and are pending. Claim 45 and 46 have been canceled without prejudice and without acquiescence. Claims 1, 8-10, 15, 16, 26, 27, 28, 31, 32, and 38 have been amended without prejudice and without acquiescence to clarify the claim scope. Support for the amendments can be found in the original pending claims. Applicants retain the right to file any divisional and/or continuation applications from any canceled subject matter. No new matter has been added.

The issues outstanding in this application are as follows:

- Claims 8-10, 15, 16, 28, 30 and 46 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

- Claims 1, 7-10, 14-19, 26-32, 38-40, 45 and 46 have been rejected under 35 U.S.C. §103(a), as being unpatentable by Van Bree et al. (WO 01/72322).

Applicants respectfully traverse the outstanding rejections and objections, and applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. U.S.C. §112, second paragraph

Claims 8-10, 15, 16, 28, 30 and 46 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended without acquiescence and without prejudice claims 8-10, 15, 16, 28 and 30 to clarify the claims. In view of these amendments, Applicants request withdrawal of the rejection.

Regarding claim 46, Applicants assert that the Examiner has not established a *prima facia* case of indefiniteness. Definiteness of claim language must be analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application

disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *See In re Moore*, 439, F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA).

Throughout the entire Specification, more specifically, paragraphs [0042] and [0069], Applicants describe that the lactoferrin composition comprises lactoferrin, a portion or part of lactoferrin, an N-terminal variant or a combination thereof. Thus, one of skill in the art would understand that the composition could comprise lactoferrin, as well as about 1% to about 50% N-terminal variants. Thus, Applicants assert that the terms are clearly defined. Applicants remind the Examiner that "acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." See MPEP 2173.05(b).

In view of the above amendments and arguments, Applicants request that the rejection be withdrawn.

I. 35 U.S.C. §103(a)

Claims 1, 7-10, 14-19, 26-32, 38-40, 45 and 46 have been rejected under 35 U.S.C. §103(a), as being unpatentable by Van Bree et al. (WO 01/72322). Applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have amended without acquiescence and without prejudice claims 26, 27, 31, 32 and 38 to indicate that the lactoferrin composition comprises at least 1% to about 50% of N-terminal lactoferrin variants. Applicants assert that Van Bree et al. do not mention or suggest that the lactoferrin composition can comprise at least 1% to about 50% of N-terminal lactoferrin variants.

The Examiner indicates that Van Bree et al. do teach a concentration of polypeptides of at least 1% to 20% by weight (page 24, lines 10-12; page 25-, lines 22-24). However, the Examiner has misinterpreted the meaning of this % by Van Bree et al. Van Bree et al. describes that the concentration of the lactoferrin polypeptide (lactoferrin or lactoferrin variant) can vary widely from about 0.1% to 20% by weight of the pharmaceutical composition. Thus, the **total concentration** of lactoferrin in the composition is 0.1% to about 20% with the remaining 99% to 80% of the composition being pharmaceutical carriers.

The present claims refer to not the total concentration of lactoferrin in the pharmaceutical composition, but the amount of N-terminal lactoferrin variant compared to non N-terminal lactoferrin variant (See paragraph [0077]). In view of this distinction, Applicants assert that no where in Van Bree et al. is there a suggestion of the total lactoferrin concentration comprising at least 1% to at least 50% is an N-terminal lactoferrin variant. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in the Van Bree. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02703US2 from which the undersigned is authorized to draw.

Dated:

Respectfully submitted,

By

Melissa W. Acosta, Ph.D.
Registration No.: 45,872
FULBRIGHT & JAWORSKI L.L.P.
Fulbright Tower
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5151
(713) 651-5246 (Fax)
Agent for Applicant